REMARKS

Claim 9 is currently pending in the present application. Claims 5-8 have been cancelled. Claims 1-4 and 10-15 have been withdrawn as directed to non-elected subject matter.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

1. Rejection of Claim 9 under 35 U.S.C. § 102(a)

Claim 9 stands rejected under 35 U.S.C. § 102(a) as being unpatentable in view of Houston et al. (U.S. Published Application No. 2004/0071685).

Applicant respectfully traverses the rejection of claim 9 under 35 U.S.C. § 102(a).

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. R*ichardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

Claim 9 is directed to a medicament capable of substituting or complementing hormone replacement therapy, said medicament consisting at least in part of **an extract obtained by concentration of an extract fluid from *Cimicifuga racemosa* in the presence of an effective amount of poly(vinylpyrrolidone)** as a solvent mediator.

In contrast, Houston et al. is directed to a composition and method for increasing the bioavailability of an aglycone in a subject. The composition comprises at least two enzymes, for example, a xylanase, a glucanase, or a glucosidase. A method for converting a glycosylated isoflavone into an aglycone in a digestive tract of a subject, comprising orally administering an effective amount of a composition comprising at least two enzymes, for example, a xylanase, a beta-glucanase, or glucosidase, and concomitantly administering a food stuff, for example, glycolsylated isoflavone.

Houston et al. does not teach a medicament consisting at least in part of **an extract obtained by concentration of an extract fluid from *Cimicifuga racemosa* in the presence of an effective amount of poly(vinylpyrrolidone)** as recited in present claim 9. In fact, Houston et al. teach an extract prepared in a conventional manner, i.e., without the presence of polyvinylprrolidone (PVP) during extraction. Acceding to Houston et al, PVP is added as an excipient to an "enzyme" which may be an extract obtained from black cohosh (cimicfuga). Specifically, Houston et al. disclose:

> In making the compositions of the present invention, the enzyme(s) can be mixed with a pharmaceutically acceptable excipient, diluted by the excipient or enclosed within such a carrier, which can be in the form of a capsule, sachet, paper or other container. Some examples of suitable excipients include lactose, dextrose,

> sucrose, sorbitol, mannitol, starches, gum acacia, calcium phosphate, alginates, tragacanth, gelatin, calcium silicate, microcrystalline cellulose, polyvinylpyrrolidone, cellulose, water, syrup and methyl cellulose. *See* Houston et al. at paragraph 83.

Accordingly, Applicant submit the extract taught in Houston et al. is not the same as presently claimed extract. Therefore, Applicant submit Houston et al. does not teach each and every element of the presently pending claim as required for anticipation under 35 U.S.C. § 102(a).

In the Official Action, the Examiner states:

> ...the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. *See* the Official Action at page 4.

Applicant respectfully submits such a distinction can be gleaned from the present specification in Figures 1 and 2 and the corresponding explanation in Examples 3 and 4. More specifically, Applicant submits the specification provides clear proof that extracts according to the presently claimed subject matter, i.e., extracts prepared in the presence of PVP, are distinguishable form extracts produced by conventional means, i.e., not in the presence of PVP.

The present specification clearly delineates the

difference between the extract according to the presently claimed subject matter and that according to extracts produced by conventional means. For example the present specification discloses:

> Analytical results of three batches prepared according to example 1 gave the following triterpene glycoside values: 8.34%, 8.84% und 10.04% or an average of 9.07% corresponding to at least 6% if calculated as 27-deoxy acetein, the substance conventionally used for standardization of extracts of *Cimicifuga racemosa*.
>
> These values indicate a most desirable high concentration, notably when considering the fact that the final product contains about 25% of PVP. **Conventional extracts of *Cimicifuga racemosa* have a substantially lower content of triterpene glycosides and appear to be less effective at equivalent dosages.** The higher and apparently distinctive content of triterpene glycosides in an extract according to the invention is not due to an enrichment procedure but merely upon application of the method according to the invention providing for a recovery of active plant ingredients without loss.
>
> In vitro testing of *Cimicifuga racemosa* extract obtained according to the invention indicates binding to distinguishable somatic receptors as well as to receptors in the central nervous system so as to make such extracts a valuable candidate for alleviating climacteric and menopausal symptoms. (Emphasis added). *See* the present specification at page 11, lines 6-20.

Accordingly, Applicant submits the specification provides a clear indication an extract produced in the presence of PVP is a materially different extract than an

extract produced in the absence of PVP. Specifically, as disclosed in the passage of the specification reproduced above, the extracts according to the presently claimed subject matter because conventional extracts of *Cimicifuga racemosa* have a substantially lower content of triterpene glycosides and appear to be less effective at equivalent dosages.

In further support of the patentability of the presently claimed subject matter, Applicant submits the skilled according to prior art compositions a skilled artisan would not have been lead to believe that presence of the prior art excipients, such as PVP, during extraction would significantly alter the composition of the extract. Therefore, based on the prior art teachings a skilled artisan would expect a composition with a lower content of pharmaceutically active ingredients if the PVP added during production of the extract was allowed to remain in the extract. The presently claimed subject matter, as supported by the present specification, provides other wise.

Accordingly, Applicant submit Houston et al. do not teach each and every element of claim 9, as required for anticipation under 35 USC § 102(a). Therefore, Applicant respectfully request that the Examiner reconsider and withdraw the rejection of claim 9 under 35 USC § 102(a).

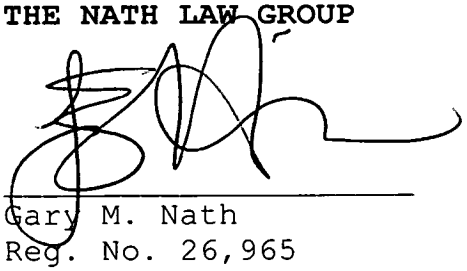
CONCLUSION

In view of the foregoing, Applicant submits the pending claims are in condition for allowance. Early notice to this effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed such contact will expedite the prosecution of the application.

If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

Respectfully submitted,

THE NATH LAW GROUP



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